K060438 (pg 1 of 2)

TORNIER

Implants Chirurgicaux

APR 19 2006

# Summary of Safety and Effectiveness information
## *510(k) Premarket Notification – RHS*

**Regulatory authority:** Safe Medical Devices Act of 1990, 21 CRF 807.92

**1) Device name**

| | |
|---|---|
| **Trade name:** | ***RHS*** |
| **Common name:** | Radial head prosthesis |
| **Classification name:** | 888.3170 Elbow joint radial (hemi-elbow) polymer prosthesis<br>888.3160 Elbow joint metal/polymer semi-constrained cemented prosthesis |

**Classification number:**

**2) Submitter**

Tornier
Rue Doyen Gosse
38330 Saint Ismier - France

**3) Company contact**

Tornier
Mrs Mireille Lémery
Regulatory affairs Manager
161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex - France
Tel: 00 33 4 76 61 38 98
Fax: 00 33 4 76 61 35 33
e-mail : mireille.lemery@tornier.fr

**4) Classification**

| | |
|---|---|
| **Device class:** | Class II |
| **Classification panel:** | Orthopedic |
| **Product code:** | JDB &KWI |

**5) Equivalent / Predicate device**

Radial Head Prosthesis, Tornier, K994041
Radial Head, Avanta, K023604
Explor, Biomet, K051385



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S.A.S. au capital de 288 000 €
SIRET : 070 501 275 000 13
R.C.S. : 070 501 275
CODE APE : 331 B

SIEGE SOCIAL : rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

TORNIER
Implants Chirurgicaux

**6) Device description**

The RHS has been designed in order to provide surgeons and patients with a joint prosthesis to restore function and relieve pain of the radial part of the elbow joint. The RHS has an anatomical design, which reproduces the kinematics of the radial joint. The RHS consists of two components: a metal radial stem and a metal-polyethylene radial head.

**7) Materials**

The radial head is made of ultra high molecular weight polyethylene (UHMWPE), with a chromium-cobalt alloy (CoCr) shell. The stem is made of chromium-cobalt alloy. Some stems are plasma-spray coated with titanium.

**8) Indications**

The RHS is intended for:

1) Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
    a. Joint destruction and/or subluxation visible on x-ray
    b. Resistance to conservative treatment
2) Primary replacement after fracture of the radial head
3) Symptomatic sequelae after radial head resection
4) Revision following failed radial head arthroplasty

The long stem is for single cemented use only. The short stem coated with titanium plasma-spray is for single use with or without cement.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tornier
c/o Mrs. Mireille Lémery
Regulatory Affairs Manager
161, rue Lavoisier – Montbonnot
38334 Saint-Ismier Cedex
FRANCE

APR 1 8 2006

Re: K060438
Trade/Device Name: RHS
Regulation Number: 21 CFR 888.3160
Regulation Name: Elbow joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDB, KWI
Dated: February 16, 2006
Received: February 27, 2006

Dear Mrs. Lémery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** K060433

**Device Name:** RHS

**Indications For Use:**

The RHS is intended for:

1) Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
   a. Joint destruction and/or subluxation visible on x-ray
   b. Resistance to conservative treatment
2) Primary replacement after fracture of the radial head
3) Symptomatic sequelae after radial head resection
4) Revision following failed radial head arthroplasty

The long stem is for single cemented use only. The short stem coated with titanium plasma-spray is for single use with or without cement.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K060433